

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/764,861 01/26/2004		Paul T. Jacobs	JJM-408 CON1 9404		
27777 7	590 07/26/2006		EXAM	EXAMINER	
PHILIP S. JOHNSON			MCKANE, ELIZABETH L		
JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ART UNIT	PAPER NUMBER	
			1744		

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applica	ation No.	Applicant(s)				
Office Action Summary			,861	JACOBS ET AL.				
			ner	Art Unit				
		Leigh N		1744				
Period fo	The MAILING DATE of this communica or Reply	tion appears on	the cover sheet with the c	correspondence addre	ss			
A SH WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE MAIL nsions of time may be available under the provisions of 3 SIX (6) MONTHS from the mailing date of this communic period for reply is specified above, the maximum statute to reply within the set or extended period for reply will, reply received by the Office later than three months after ed patent term adjustment. See 37 CFR 1.704(b).	ING DATE OF 7 CFR 1.136(a). In no cation. bry period will apply and by statute, cause the	THIS COMMUNICATION event, however, may a reply be tind will expire SIX (6) MONTHS from application to become ABANDONE	N. nely filed the mailing date of this commi D (35 U.S.C. § 133).				
Status								
1)⊠	Responsive to communication(s) filed of	on <i>02 May 2006</i>						
· —		☐ This action is						
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
,—	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Dispositi	on of Claims	·						
· _		lication						
	 ✓ Claim(s) <u>1-20</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 							
) Claim(s) is/are allowed.							
· ·	⊠ Claim(s) <u>1-20</u> is/are rejected.							
	Claim(s) is/are objected to.							
·	8) Claim(s) are subject to restriction and/or election requirement.							
	on Papers							
	The specification is objected to by the E	veminer						
	- ·		conted or h) objected	to by the Everniner				
10)⊠ The drawing(s) filed on <u>26 January 2004</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
			•	, ,	l 121(d)			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
	inder 35 U.S.C. § 119							
12)	Acknowledgment is made of a claim for	foreign priority (under 35 U.S.C. § 119(a))-(d) or (f).				
a)į	☐ All b)☐ Some * c)☐ None of: 1.☐ Certified copies of the priority dod	arraa aada aharra da	i d					
	1. Certified copies of the priority doc2. Certified copies of the priority doc			an Na				
	3. Copies of the certified copies of t		· ·		20			
				d iii tiiis National Sta	.g _e			
* 5	application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
			. amou copido mot rocomo					
Attachmen			🗖	11				
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date								
Notice of Dialisperson's Patent Diawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 012604. 5) Notice of Informal Patent Application (PTO-152) 6) Other:								
Detect and T	-demand Office							

Application/Control Number: 10/764,861 Page 2

Art Unit: 1744

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1-7, 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forstrom et al. (U.S. Patent No. 4,169,124) in view of Cummings et al. (U.S. Patent No. 4,744,951).

As to claims 1-7, 9, and 10, Forstrom et al. discloses a method of hydrogen peroxide sterilization wherein a small amount of dilute hydrogen peroxide 12 is introduced into a chamber 1, along with an article 9,10 to be sterilized, and the hydrogen peroxide then vaporized to sterilize the article. Vaporization occurs when the chamber is evacuated through diffusion restriction 5. See col.4, lines 4-25; Figure 1 and 2. Forstrom et al. does not teach selectively drawing water vapor from the chamber to increase a ratio of hydrogen peroxide to water in the chamber.

Cummings et al. teaches a method of sterilizing wherein an article is placed into a sterilizing chamber 22, the chamber is evacuated (dried), a dilute (0.05-5%) aqueous solution of H_2O_2 is introduced into an enclosure 10 having a diffusion restriction 20 in fluid communication with the chamber 22 and vaporized. Thereafter, water vapor is drawn off through port 14 to increase the ratio of H_2O_2 to water and the H_2O_2 is subsequently furnished to the article within evacuated chamber 22 for sterilization. See Figure and col.3, lines 29-55. Cummings et al.

Art Unit: 1744

discloses that "conditions within the chamber" are controlled to cause the preferential vaporization of water from the solution. As shown in the Examples, the pressure and temperature are controlled to achieve this preferential vaporization. Cummings et al. discloses a preferred final concentration of hydrogen peroxide (50-80%), which encompasses the claimed ratios.

It would have been obvious to one of ordinary skill in the art to preferentially remove the water vapor from the generated vapor of Forstrom et al. since Cummings et al. teaches that doing so yields a higher peroxide concentration and thus, an improved sterilization efficacy. See Examples 3-5.

With respect to claims 11-19, it is known to those in the art that vaporization of a component of a solution occurs when the vapor pressure of the component exceeds that its surroundings. This vaporization can be achieved by increasing the vapor pressure of the component through two means: heating the solution to increase the vapor pressure thereof or lowering the surrounding pressure. (See for example Forstrom et al. which teaches imposing a vacuum on the chamber in combination with heat to promote vaporization of the solution.)

Thus, it would have been obvious to control both of these parameters in any desired combination or order in order to control vaporization of the water from the solution and to achieve the desired final concentration of hydrogen peroxide, as taught by Cummings et al..

Application/Control Number: 10/764,861 Page 4

Art Unit: 1744

3. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Forstrom et al. in view of Cummings et al. as applied to claim 18 above, and further in view of Spencer et al. (U.S. Patent No. 5,656,238).

Forstrom et al. discloses imposing a vacuum on the chamber in order to dry the chamber but does not teach applying energy thereto. Spencer et al. teaches that the application of a plasma during an initial evacuation step promotes drying of the chamber and allows a desired pressure to be attained more quickly than without the plasma. See Abstract. For these reasons, it would have been obvious to apply energy during the drying step of the combination *supra*.

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claims 1-20 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-20 of prior U.S. Patent No. 6,656,426 (cited on the IDS of 26 January 2004). This is a double patenting rejection.

Information Disclosure Statement

6. The German document on the information disclosure statement filed 26 January 2004 has been considered in view of the Abstract filed 2 May 2006.

Terminal Disclaimer

7. The terminal disclaimers filed on 2 May 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,325,972 and 6,627,150 have been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (5:30 am-3:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

Application/Control Number: 10/764,861

Art Unit: 1744

Page 6

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Luch Mucane Leigh McKane

Primary Examiner

Art Unit 1744

elm

12 July 2006